HB 615: Cancer Clinical Trials
Approved Study Plan

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A. INTRODUCTION

With the passage of HB 615, the 2011 Legislature directed the Office of the Commissioner of Securities and Insurance (CSI) to study issues related to the equitable treatment by insurers for cancer patients seeking to participate in cancer clinical trials.

HB 615 directs CSI to:

- Convene an advisory committee of representatives of insurance, reinsurance, and self insurance offerors in Montana, as well as patients, health care advisors, providers, and administrators;
- Assess whether violations of Montana statutes are occurring related to this denial of care or ineligibility of coverage and take appropriate action if any are found;
- Review a selection of other states' policies related to required treatment of cancer routine care coverage for insureds undergoing clinical trials; and
- Summarize and present findings and recommendations to the Children, Families, Health and Human Services Committee on or before March 31, 2012.

HB 615 directs the advisory council to:

- Evaluate the causes of the routine care coverage denials or exclusion for patients recommended for participation in cancer clinical trials;
- Indentify necessary federal policy changes to address denials or exclusion for the purchasers of ERISA-regulated health care plans;
- Define routine care for cancer patients undergoing clinical trials; and
- Make findings and recommendations to address the above items.

B. BACKGROUND ON INSURANCE COVERAGE FOR CANCER PATIENTS ENGAGED IN CLINICAL TRIALS

Sections will be enhanced and completed throughout the study for inclusion in final report

- Description of the problem

Some cancer patients in Montana and around the country who have private insurance coverage find that treatment of their routine care is not covered when they join or consider joining cancer clinical trials. Insurance company officials may consider the treatment to be “experimental or investigational” and thus judge it to have an unknown, but possible impact on the cost of routine care. They may believe the sponsor of the trial should cover more of the costs.

The denial of coverage is difficult for patients and their families who believe the trial provides treatment that may increase the quality or length of life. Most often those patients do not have the energy to appeal their insurance plan’s decision to deny courage of routine care. It also concerns researchers and policy makers who understand the importance of clinical trials for the advancement of treatment and potential for finding cures for illnesses that take a heavy toll on the population, social structures, and public resources.

- Montana research on the topic

The Office of the Commissioner of Securities and Insurance (CSI) is the state agency most likely to collect data on insurance coverage. Absent any legal requirement to collect specific data on coverage denials or exclusions of routine care for patients undergoing clinical trials, the office has not used its resources and its authority to request information from insurance companies for this purpose. CSI will examine its ability to request additional data for the purpose of making a data-driven assessment of the extent of the problem in Montana.

The Montana Cancer Consortium is a nonprofit organization whose mission is to bring "state of the art" cancer treatment to Montana through clinical trials sponsored by the National Cancer Institute (NCI). The group works with oncologists across the state to manage grants from NCI for clinical trials. The Consortium does not track denials of coverage for patients hoping to participate in clinical trials.

Members of the Cancer Clinical Trials (CCT) Advisory Council will be asked to provide information or resources with which they are familiar.

- Anecdotal stories from patients and providers in Montana

Several Montanans testified at the 2011 legislative session about their experience with coverage difficulties when considering clinical trials.

**Insert summaries of stories from the legislative hearings*

CCT Advisory Council will receive public comment from patients and families, providers, patient advocates and insurance company representatives throughout the course of the study.

- Current practice by insurers in Montana

Insurance companies consider the patient costs of those hoping to enter clinical trials on a case-by-case basis. They often cover routine care after consideration of the trial protocol. Many companies administer self-funded plans for large employers. The contractual agreement in those plans will govern when there is an appeal of their decision to deny coverage. The initial decision to deny is generally based on the company's policies and definitions regarding "medical necessity" and "investigational and experimental." CCT Advisory Council members will be asked to provide additional information to clarify current practice and policy.

- The issue across the states and how states have responded

It is clear that other states consider the coverage of routine care for cancer patients undergoing clinical trials to be of concern; Beginning in 1995, 34 states and Washington, D.C have passed laws or implemented agreements requiring coverage. Following the example of the states, Congress included a provision requiring such coverage under the Patient Protection and Affordable Care Act (ACA) in 2010. Rules implementing the section are anticipated in the coming year and will be examined by the CCT Advisory Council. Medicare has required coverage since at least September 2000 and Medicare's National Coverage Decisions (NCD) will be considered by the Advisory Council.

Various state laws and compacts will be considered by CSI staff and the CCT Advisory Council in the course of the study. Empirical data from national and other state sources will be sought and examined if available.

- History of 2007 effort in Montana

SB 428, requiring coverage of routine costs for cancer patients in clinical trials, was introduced during the 2007 Montana Legislative Session. The bill passed through the Senate with support from patients, providers, and insurers with the understanding that reinsurance issues needed to be addressed once the bill reached the Montana House of Representatives. Consensus could not be reached in the limited amount of time. The bill was tabled with the understanding that cancer care providers, payers, and patient advocates would work toward resolving this important health care issue. A collaborative consensus solution was to be formulated by those most involved in the issue.

The resulting Montana Working Group to Improve Access to Clinical Trials was a consortium of the major stakeholders in the care of Montana's cancer patients. The charge of the group was to improve access to clinical trials by undertaking the following:

1. To define routine care
2. To clarify clinical trial terminology
3. To develop and implement operational processes for smooth enrollment and continuation of participation
4. To educate impacted parties about the agreement and help implement it

Three Subcommittees of the Working Group were established on June 14, 2007 and assigned to draft portions of a voluntary agreement that would provide the framework for coverage of patient care costs for those enrolled in clinical trials within the scope of the individual's benefit plan:

1. Definitions workgroup: Draft the definition of routine care and clarification of clinical terminology.
2. Operations workgroup: Draft guidelines and operational processes
3. Implementation workgroup: Draft steps for targeted statewide education and implementation.

At one point during the process, the working group described its purpose and activities in this way:

> "The Montana Working Group to Improve Access to Clinical Trials believes this agreement would improve research study recruitment and Montana's cancer patients' access to clinical trials as a treatment option without risk of personal financial burden. Cancer clinical trials provide outcomes data necessary to assess medical practice and build on evidence based, value driven health care. Scientific oversight helps to focus rational decision making within these studies. Montana healthcare payers could benefit from the advancement in science, [the] avoidance of useless treatment, and [the] continuous quality improvement cancer care clinical research provides.
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> The goal of this agreement is to increase participation in select cancer-related clinical trials by making payment for services provided within the context of clinical trials …predictable. After serious consideration of these concerns and discussion of the rationale for supporting clinical research efforts in Montana, the group agreed that health plans* should be willing to provide coverage for the routine care costs of patient participation in approved clinical trials."

Draft language for a "consensus agreement" on definitions was written up in October 2007, but consensus was not reached. The effort was abandoned shortly thereafter.

Those CCT Advisory Council members who served on the 2007 working group will be asked to discuss their experience with the 2007 effort.

- How this "study" is different than the 2007 effort

The informal process in 2007 was directed at reaching a "consensus agreement," following failed legislation. It involved negotiation between stakeholders with the hope of an outcome that reflected an agreement among those stakeholders that would then be implemented voluntarily. The current effort is the result of the passage of HB 615 and is designed to be a "study" not a "negotiation." The Office of the Commissioner of Securities and Insurance is directed to conduct the study and provide necessary resources. The outcome will be a report on the recommendations and findings of an official advisory committee. A negotiation process is beyond the scope of the bill. However, should the recommendations of the study include another effort at a negotiated agreement, nothing prohibits the advisory council from moving ahead immediately with such a process or the Commissioner from agreeing to continue to facilitate additional meetings of the advisory council for that purpose.

- How the climate has changed since 2007

The context in 2011 may be more conducive to progress on the issue of coverage for cancer patients' routine care while accessing a clinical trial. The Patient Protection and Affordable Care Act passed Congress in 2010. One of its provisions required the coverage of routine costs for cancer patients in clinical trials. The U.S. Department of Health and Human Services is expected to draft rules on this provision in the coming years. The National Association of Insurance Commissioners was asked to recommend model language for those rules, and has placed it on the agenda for their Regulatory Framework (B) Task Force meeting in the fall of 2011. Commissioner Lindeen is vice chair of that committee.

In addition, new scientific studies are now available about the costs and benefits of clinical trials. Providers and payers alike are exploring new models for delivering and paying for care, improving health outcomes, and using electronic medical records. Commissioner Lindeen facilitates one such effort— the Montana Medical Home Advisory Council. Finally, consumers are more engaged in the public discourse around health care. All these factors may stimulate more collaborative efforts.

C. STUDY ACTIVITIES DIRECTLY RELATED TO THE ADVISORY COUNCIL, GENERAL TIMELINES

CSI will:

- Convene an advisory committee of representatives of insurance, reinsurance, and self insurance offerors in Montana, as well as patients, health care advisors, providers, and administrators.

CSI made a general call to parties that might be interested in serving on an advisory committee in June, 2011. CSI staff examined the responses to see how they fit the representation required in the law, spoke with participants to ascertain their level of interest, contacted others to fulfill the requirements, and announced the final committee participants on August 12, 2011.

The creation of advisory councils is addressed in 2-15-122 MCA. Their purpose is only to serve in an advisory capacity as defined in 2-15-102, MCA. In short, the law sets out the duties of advisory councils as "furnishing advice, gathering information, making recommendations and …. [not] administering a program or setting policy."

The "advisory committee" addressed in HB 615 will be known as the Cancer Clinical Trials Advisory Council. The advisory council serves at the pleasure of the Commissioner and the names of its members have been filed with the governor's office and the secretary of state. The council will exist no longer than two years and the group will select a presiding officer. Official minutes will be taken and approved and rules of quorum will be followed. Except for government employees, members will be entitled to pay and expense reimbursement.

The council will help CSI evaluate the causes of the routine care coverage exclusions and denials, indentify policy changes at the federal level necessary to address these issues in ERISA-regulated plans, define routine care for cancer patients undergoing clinical trials, make findings and recommendations to the commissioner for possible resolution of issues identified, and respond to a draft study report.

The council will meet at least four times between September 2011 and March 2012, when the final report and any recommendations are to be presented to the Interim Families Health and Human Services Committee. The council may recommend meeting more or less frequently. Meetings may be held via conference call or by other electronic means.

An interested parties list will be maintained and its members will be informed of all meetings, electronic or in-person, and encouraged to give public comment. A public web page will be available at the CSI website (www.csi.mt.gov.) There will be additional information about the council's activities and a place to sign up for the interested parties list.

The Advisory Committee will:

- Evaluate the causes of the routine care coverage denials or exclusion for patients recommended for participation in cancer clinical trials;

Patients, providers and insurers on the advisory committee will be asked to inform other committee members of their experience and perspective on the issue. Additional experts from a variety of perspectives will be invited to provide information on the problem and potential solutions. An invitation will be sent to the general public to present testimony to the committee. Comments will be recorded, synthesized, and reviewed by the committee. Recommendations for action will be discussed.

First meeting—presentations by council members, panelists, public comment, council response
Second meeting—review draft of findings, discussion of recommendations
Subsequent meetings—decide on recommendations to Commissioner Lindeen and CFHHS interim committee; review updates to draft of findings and recommendations

- Indentify necessary federal policy changes to address these issues for the purchasers of ERISA-regulated health care plans;

Members of the advisory committee with experience in self-insurance and reinsurance will be asked to inform other members on the issues related to federal regulation and thoughts about needed federal policy changes. Experts on the committee, CSI staff, and experts outside the committee will be asked to discuss ERISA-regulated health plans and federal reform as it relates to regulation of insurance regarding clinical trials. An invitation will be sent to the general public to present testimony to the committee. Comments will be recorded, synthesized, and reviewed by the committee. Recommendations for action will be discussed.

First meeting—No action
Second meeting—Presentations by council members, expert panelists, public comment, council response
Subsequent meetings—Review of draft findings, discussion of recommendations, comments on report of findings and recommendations

- Define routine care for cancer patients undergoing clinical trials;

The council will discuss the portion of the 2007 draft statement that concerns the definition of routine care for cancer patients. CSI staff and outside experts will discuss efforts in other states and national bodies on the definition of routine care. Council members and outside experts will be invited to forward definitions they believe are helpful. Council discussion and public comment will be used to narrow the focus and reach agreement on a definition for routine care

for cancer patients that will best serve the needs of Montana consumers, providers and insurers. The definition may form the basis for a negotiated agreement on coverage which may be considered by the advisory council following the study.

First meeting—panel of council members who participated in the 2007 working group, presentations by CSI or experts on other states' and national bodies' definitions, public comment, response by council.
Second meeting—continued presentations and discussion on the topic
Subsequent meetings—discussion of recommendations; review of draft findings and recommendations

- Make findings and recommendations to address the above items.

First meeting—no action
Second meeting—review initial draft findings on all topics
Subsequent meetings—review draft recommendations, present council findings and recommendations to Commissioner Lindeen.

D. OUTLINE OF ADDITIONAL STUDY ACTIVITIES, GENERAL TIMELINE

CSI will:

- Assess whether violations of Montana statutes are occurring related to this denial of care or ineligibility of coverage and take appropriate action if any are found;

There is no state law specifically requiring coverage of routine care for patients participating in clinical trials. It would be illegal, however, for an insurance company to fail to provide payment according to their contract. CSI does not currently collect routine data from insurance companies that will allow it to ascertain whether violations are occurring related to clinical trials. Absent individual consumer complaints, CSI does not have knowledge about denials of routine care coverage for patients involved in clinical trials.

To date, there has been only one complaint to CSI involving a clinical trial. The patient was covered under an ERISA plan, over which CSI has no jurisdiction. However, CSI was able to help negotiate a solution informally. Given the testimony at the legislature, it is likely that difficulty is more widespread than the anecdotal information suggests. Patients and providers in this situation may not know they can file complaints with CSI, may not believe filing a complaint would accomplish anything, are too sick or busy to file, or are able to successfully negotiate with insurance companies on a case-by-case basis.

CSI will investigate what information it would need in order to ask insurance companies to provide data that shows they are meeting their contractual obligations when patients are in clinical trials. Members of the advisory council will be asked to help CSI with its approach to this directive in the law. Once CSI knows how to effectively ask for the information, it will examine whether it has the resources to use its authority to request information from insurance companies that can provide a more systematic review of denials or exclusions of coverage for patients in clinical trials. If timing allows, the information will be collected and analyzed prior to March 20, 2011 and provided in the final report.

- Review a selection of other states' policies related to required treatment of cancer routine care coverage for insureds undergoing clinical trials;

CSI staff will conduct research from readily-available sources to provide a report to the advisory council and the interim committee. This information will be presented in general at the initial advisory council meeting and in greater depth at the second meeting. The advisory council will be invited to comment on the research.

- Summarize and present findings and recommendations to the Children, Families, Health and Human Services Committee on or before March 31, 2012.

CSI will be available at the request of the Children, Families, Health and Human Services Committee the present a final report at the committee's regularly scheduled meeting on March 19 and 20, 2012. In addition, CSI will be available to provide progress reports, either written or in person at the request of the interim committee. The advisory council will be invited to review a draft report and offer comment to the committee.

E. STUDY RESOURCES

Following are a list of initial resources that will help in the course of the study. The advisory council members will be asked to recommend additional resources.

- The National Cancer Institute at the U.S. National Institutes of Health: http://www.cancer.gov/clinicaltrials

- Centers for Medicare and Medicaid Services: http://www.cms.gov/ClinicalTrialPolicies/

- The National Conference of State Legislatures: http://www.ncsl.org/IssuesResearch/Health/ClinicalTrialsWhatareStatesDoing2008/tabid/14331/Default.aspx

- The American Cancer Society: http://www.cancer.org/Treatment/TreatmentsandSideEffects/ClinicalTrials/StateLawsRegardingInsuranceCoverage/index